## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Deshpande et al.

Serial No.: 09/791,153

Group Art Unit No.: 1644

Filed:

February 22, 2001

Examiner: Schwadron, Ronald B.

For:

Selective Binding Agents of

Confirmation No.: 7448

Osteoprotegerin Binding Protein

Docket No.: A-633A

# RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT AND PRELIMINARY AMENDMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

A response to the Notice of Non-Compliant Amendment dated July 22, 2009 and a Preliminary Amendment are filed herewith.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

#### CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted electronically through EFS-WEB to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on the date appearing below.

## **AMENDMENT**

Please amend the claims as follows.

# **Listing of Claims**

#### 1-39. (cancelled)

- 40. **(currently amended)** An antibody or antigen binding domain which recognizes a DE epitope on human osteoprotegerin binding protein (OPGbp) wherein the DE epitope comprises the amino acid sequence from residues 212 to 250 of human OPGbp as shown in Figure 29 (SEQ ID NO: 158).
- 41. **(currently amended)** An <u>The</u> antibody or antigen binding domain of <u>Claim 40</u> which recognizes a <u>wherein the</u> DE epitope <u>comprises residues 230 to 234</u> of en human OPGbp as shown in Figure 29 (SEQ ID NO: 158).
- 42. **(currently amended)** The antibody or antigen binding domain of Claim 40 or 41 wherein the DE epitope comprises which recognizes the sequence Asp-Leu-Ala-Thr-Glu of human OPGbp.
- 43. **(original)** An antibody or antigen binding domain which binds to murine OPGbp comprising the amino acid substitutions S229D, V230L, P231A, and D233E, but does not bind to murine OPGbp lacking said substitutions.
- 44. **(currently amended)** The antibody or antigen binding domain of Claims 40, 41, 42 or 43 which inhibits the formation of or activation of osteoclasts.
- 45. **(original)** The antibody or antigen binding domain of Claims 40, 41, 42 or 43 which inhibits bone resorption.

#### 46-51. (cancelled)

- 52. **(currently amended)** An <u>The</u> antibody or antigen binding domain of Claims 40, 41, 42 or 43 which binds selectively to human OPGbp with a dissociation constant (KD) of about 1nM or less.
- 53. **(currently amended)** An <u>The</u> antibody or antigen binding domain of Claims 40, 41, 42 or 43 which binds selectively to human OPGbp with a dissociation rate constant (kd) of about 3 x 10-3 or less.
- 54. **(new)** The antibody or antigen binding domain of Claims 40, 41, 42 or 43 wherein the antibody is a monoclonal antibody.
- 55. **(new)** The antibody or antigen binding domain of Claims 40, 41, 42 or 43 wherein the antibody is a chimeric, humanized, human, single chain or bispecific antibody.
- or 43 wherein the antigen binding domain is a Fab, F(ab'), F(ab)', Fv or sFv fragment.
- 57. **(new)** The antibody or antigen binding domain of Claims 40, 41, 42 or 43 which comprises an IgG isotype.
- 58. **(new)** A composition comprising the antibody or antigen binding domain of Claims 40, 41, 42 or 43 and a pharmaceutically acceptable agent.

# Remarks/Arguments

#### The Claims

Claims 10-20, 27-29 and 40-53 are currently pending in the application with Claims 48-51 being withdrawn from further consideration as being drawn to a non-elected species.

# **Notice of Non-Complaint Amendment**

In the communication of July 20, 2009, the Examiner noted that the amendments filed on December 19, 2007 and March 24, 2004 were considered non-compliant because Claims 48-51 drawn to non-elected species and withdrawn from further consideration were not indicated as "withdrawn" in the listing of claims.

Claims 48-51 have been cancelled in the Preliminary Amendment filed herewith, thereby bringing the amendment into compliance.

#### **Preliminary Amendment**

Applicants hereby cancel Claims 10-20, 27-29 and 46-51 without prejudice or disclaimer and add new Claims 54-58. Upon cancellation of these claims, Claims 40-45 and 52-58 will be pending in the application.

Claim 40 has been amended to recite an antibody or antigen binding domain which recognizes a DE epitope on human OPGbp "wherein the DE epitope comprises the amino acid sequence from residues 212 to 250 of human OPGbp as shown in Figure 29 (SEQ ID NO: 158)". Support for this amendment is found at p. 38, line 33 to p. 39, line 5 of the specification.

Claim 41 has been amended to recite a DE epitope that "comprises residues 230 to 234 of human OPGbp". Support for this amendment is found at p. 39, lines 12-18 of the specification.

New Claims 54-58 are supported at various locations in the specification, including p. 32, lines 8-12; p. 33, lines 5-12; and p. 72, lines 8-12 of the specification.

The new and amended claims do not add new matter or raise new issues requiring further searching and consideration. Applicants respectfully request entry of the new and amended claims.

#### CONCLUSION

Claims 40-45 and 52-58 are in condition for allowance and a notice thereof is solicited.

Although Applicants believe that no fee is due herewith, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 01-0519 in the name of Amgen Inc.

Respectfully submitted,

Robert B. Winter

Attorney/Agent for Applicant(s)

Registration No.: 34,458 Phone: (805) 447-2425 Date: August 21, 2009

Please send all future correspondence to: 21069
US Patent Operations/RBW
Dept. 4300, M/S 28-2-C
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

Electronic Acknowledgement Receipt				
EFS ID:	5935579			
Application Number:	09791153			
International Application Number:				
Confirmation Number:	7448			
Title of Invention:	Selective binding agents of osteoprotegerin binding protein			
First Named Inventor/Applicant Name:	Rajendra V. Deshpande			
Correspondence Address:	U.S. Patent Operations/RBW  Dept. 4300, M/S 27-4-A  AMGEN, INC.  One Amgen Center Drive  Thousand Oaks  CA  91320-1799  US  -			
Filer:	Robert B. Winter/Nola Diamond			
Filer Authorized By:	Robert B. Winter			
Attorney Docket Number:	A-633A			
Receipt Date:	21-AUG-2009			
Filing Date:	22-FEB-2001			
Time Stamp:	22:12:26			
Application Type:	Utility under 35 USC 111(a)			
Payment information:				

# **Payment information:**

Submitted with Payment	no
File Listing:	

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	NPL Documents	SimonetCell1997.pdf	1137987	no	11
Warnings:		C	065430e09e5d4f90b1a7bd9e331344b73ea 5266a		
Information:					
illiorillation:				I	
2	NPL Documents	Skolnick Trends In Biotech 2000. pdf	6195199 	no	6
			4273		
Warnings:					
Information:					
3	NPL Documents	SmithCell1994.pdf	483706	no	5
	W E Documents	Similar centro 574.par	7e3fcdd5aa6fe097fc2edc1ed8af4bafc7543 708		
Warnings:		I	I	<u> </u>	
Information:					
4	NPL Documents	StamenkovicEMBO_J1989.pdf	816885	no	8
4	NPL Documents	StamenkoviceMBO_J1989.pdi	5f55839f9c034a30899b790dab5cc5a85318 b877	no	٥
Warnings:					
Information:					
5	NPL Documents	StressgenProdUseSheet- RANKL_TRANCEMonoclonalAB-	73049	no	1
		Clone12A668.pdf	4093988f90bf58b0d23b77ab5fa628e72e2a df83		
Warnings:					
Information:					
_			491833	_ no	_
6	NPL Documents	SudaBone 1995.pdf	971d8f6cebb3d9d1f1d5cee4c96ce35596a 2829b		5
Warnings:			20290		
Information:					
_	ND D	SudaEndocRevMonograph199 5.pdf	467505		_
7	NPL Documents		304fcfb705530a6ca31d77cf1182221b890a 9d8d	_ no	5
Warnings:					
Information:					
8	NPL Documents	SudaEndocrineRev1999.pdf	1273553	no	14
0	NFL Documents		de46004c12cbaa48fed6838855f3d168180 6f453		
Warnings:					
Information:					
9	NPL Documents	TakadaBoneMineral 1992.pdf	1782601	no	15
		99	92d95be93c06c09ce0e758693fe465f41c99 6226		

Warnings:					
Information:					
10	NPL Documents	TakeyamaBiochemBiophysRes	438718	no <sub>30</sub>	6
		Comm2000.pdf	e9db9be6c988e00066f9d35440054092d80 cebac		
Warnings:					
Information:					
11	NPL Documents	TengJClinInvest2000.pdf	1278975	no	18
			4f94f42e9fdd87e353d4a91eb78ef167c74fd 2ef		
Warnings:					
Information:					
12	NPL Documents	TsudaBiochemBiophysResCom	549605	no	7
		m1997.pdf	cc82556da8ab656bedda3378b90b5c10b1 22e40b		
Warnings:					
Information:					
13	NPL Documents	UdagawaBone 1999.pdf	682032	no	8
			01f05e1b380a781fb4d9d2e22f1154a66b36 9213		
Warnings:					
Information:					
14	NPL Documents	VineyJlmmunol1998.pdf	367004	no	11
			fb04f558880fa926e97d85b3b7c2fdc46298 8e42		
Warnings:					
Information:					
15	NPL Documents	WatanabeBiochemBiophysRes	876623	no	8
		Comm1990.pdf	8ad0073cceddf68a3ce2ff0930a68a359dc0 2478		
Warnings:					
Information:					
16	NPL Documents	WillardProteinExpressionPurific	922887	no	11
		ation 2000.pdf	cf343435fcdf8488aee25f06f9b0d5d981a53 da1		
Warnings:		<u> </u>			
Information:					
			421575	no 12	5
17	NPL Documents	WongJBiolChem1997.pdf _	d87cc4d5e5d1591597f34bf91a03879c3a42 4ff4		
Warnings:					
Information:					
18	NPL Documents	ShalhoubJCellBiochem1999.	3615910	no	11
		pdf	a04ebe6ccc90e00f4dc9acb06f6e9b166efcf 3ff		11

Warnings:					
Information:					
19	NPL Documents	SudaEndocRev1992.pdf	1161023	no	1
		'	de6d21c9cf6be8bce2c6877f917283b9a8d 2d255		
Warnings:					
Information:					
20	NPL Documents	WileyImmunity1995.pdf	8407990	no	10
			42c6927b6cf9686332f89b1829ae02a85c81 910b		
Warnings:					
Information:					
21	NPL Documents	WongJExpMed1997.pdf	5188582	no	6
			79a4bb3c911681580ea761edbbb2f274f4fa 49e6		
Warnings:					
Information:					
22	NPL Documents	WongJBiolChem1998.pdf	402415	no	5
			3e5ace7a0dc09c739c952817e237bf9a07a3 826d		
Warnings:					
Information:					
23	NPL Documents	Xulmmunity1996.pdf	686913	no	9
			fc2e5834dfa5fcb1d3e1d536d3d68c8fd77c 8ff4		
Warnings:					
Information:					
24	NPL Documents	YangProcNatlAcadSciUSA1985.	4566471	no	5
		pdf	f6322bc8fff1badcbed33e76cb1a0ec12b98 670c		
Warnings:					
Information:					
25	NPL Documents	Yasuda PNAS 1998. pdf	336481	no	6
23	W E Bocaments	rasaaar w.s.rsso.par	fb64b7f3341a5b2dc135f62d93c27725c5a5 3618	110	
Warnings:					
Information:					
			550720	no	6
26	NPL Documents	YonedaCancerRes1995.pdf -	fbd3ac35de66eabeb6d39fa4c020d2d5a19 081f8		
Warnings:					<u> </u>
Information:					
27	NPL Documents	Yunlmmunol1998.pdf	1303007	no	9
_,	5000		da9132587d5cf06c8fb694f2ee6c8dab86e3 062a		

Warnings:					
Information:					
28	NPL Documents	Zhang JBiol Chem 2001. pdf	568959	no	6
		,	6222e3fcc4807f48eaea2d8db7d6034703f2 1a0d		
Warnings:					
Information:					
29		HymowitzBiochemistry2000.	545746	no	8
		pdf	9386392e2faa71a05ee42534726bf4f302c1 7726		
Warnings:					
Information:					
30	NPL Documents	Mongkolsapaya Nature Struct Bi ol 1999.pdf	6938798	no	6
		011999.pd1	2991525adfe1ef61aae4ed8e678a9646e3eb 604d		
Warnings:					
Information:					
31	NPL Documents	Parslow Med Immunology 1997.	1810718	no	11
		pdf	d31ae84908fc0659b0940b1b7e805c906d8 499d4		
Warnings:					
Information:					
32	NPL Documents	Chalmmunity1999.pdf	8632804	no	9
		, , , , , , , , , , , , , , , , , , , ,	1c1c23b1549ceb28dbc5fa3c66ea0db65cd 5e09f		_
Warnings:					
Information:					
33	Information Disclosure Statement (IDS)	A-633ASupp1449-5of5-082109.	600762	no	2
	Filed (SB/08)	pdf	6d64a1c02de140d0ea3ce918e0d4cd57753 d4d92		
<b>Warnings:</b>					
Information:					
This is not an U	SPTO supplied IDS fillable form				
34	Dower of Attornov	060000	51685		1
34	Power of Attorney	A-633APowerOfAtty082109.pdf	0d72edd4d4ddc7fc14111f317652d3969c9 71061	no	1
Warnings:					-
Information:					
		A-633A-	155654	yes	5
	35 Respo	Response To Notice 082109.pdf	18c6ce811fdbc6a375421a044864d4c0f8e2 f730	1	
Multipart Description/PDF files in .zip description					
	Document Description		Start	End	

Total Files Size (in bytes): 63784375			784375
Information:			
Warnings:			
	Applicant Arguments/Remarks Made in an Amendment	4	5
	Claims	2	3
	Preliminary Amendment	1	1

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.